

FORM PTO -1083
MAIL STOP: AMENDMENT
COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: 300.1005CON
Date: August 10, 2005

In re application of: Chih-Ming CHEN, et al.
Serial No.: 10/796,411
Filed: March 9, 2004
For: **CONTROLLED RELEASE METFORMIN COMPOSITIONS**

Transmitted herewith is a **Supplemental Information Disclosure Statement** in the above-identified application.

- ☐ Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.
- ☐ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.
- ☒ No fee for additional claims is required.
- ☐ A filing fee for additional claims calculated as shown below, is required:

| FOR: | (Col. 1) | (Col. 2) | SMALL ENTITY | | OR | LARGE ENTITY | |
|---|----------------|------------|--------------|-----|----|--------------|-----|
| | REMAINING | HIGHEST | RATE | FEE | | RATE | FEE |
| | AFTER | PREVIOUSLY | x \$ | 9 | | x \$ | 18 |
| | AMENDMENT | PAID FOR | | | | | |
| TOTAL CLAIMS | * Minus 20** = | PRESENT | x \$ | 43 | | x \$ | 86 |
| INDEP. CLAIMS | * Minus 3*** = | EXTRA | x \$ | 145 | | x \$ | 290 |
| [] FIRST PRESENTATION OF MULTIPLE DEP. CLAIM | | | + | \$ | | + | \$ |

TOTAL: \$ OR TOTAL: \$.00

- * If the entry in Co. 1 is less than the entry in Col. 2, write "0" in Col. 3.
- ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, write "20" in this space.
- *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, write "3" in this space.

- ☒ Also transmitted herewith are:
- ☒ Form PTO 1449 (1 page); and
- ☒ cited reference and copy of European Search Report and Colombian opposition
- ☒ Check(s) in the amount of **\$180.00** is/are attached to cover:
- ☐ Filing fee for additional claims under 37 C.F.R. 1.16
- ☐ Petition fee
- ☒ Other: Information Disclosure Statement Fee
- ☐ Other:
- ☒ The Assistant Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. 50-0552.
- ☐ Any filing fee under 37 C.F.R. 1.16 for the presentation of additional claims which are not paid by check submitted herewith.
- ☒ Any patent application processing fees under 37 C.F.R. 1.17.
- ☒ Any petition fees for extension under 37 C.F.R. 1.136 which are not paid by check submitted herewith, and it is hereby requested that this be a petition for an automatic extension of time under 37 CFR 1.136.

Robert J. Paradiso, Reg. No. 41,240
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Tel: (212) 736-1940
Fax: (212) 736-2427

I hereby certify that this correspondence and/or documents referred to as attached therein and/or fee are being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450", on August 10, 2005.

DAVIDSON, DAVIDSON & KAPPEL, LLC

Elizabeth Pietrowski

BEST AVAILABLE COPY

UNITED STATES PATENT & TRADEMARK OFFICE

Re: Serial No.: 10/796,411
 Application of: Chi-Ming Chen, et al.
 Filed: December 27, 2004
 For: **Controlled Release Metformin Compositions**
 Examiner: Young, Micah Paul
 Art Unit: 1615
 Docket No.: 300.1005CON
 Customer No.: 23280

Mail Stop: Amendment
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

August 10, 2005

SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.56

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the document listed on the accompanying Form PTO-1449 (1 sheet) for consideration by the Examiner in connection with the examination of the above-identified patent application.

Applicants note that the enclosed reference, listed as "EL" on the attached Form PTO 1449, was listed in the European Search Report that was issued in connection with European Application No. 01991078, which corresponds to the current application. A copy of the search report is enclosed.

Additionally, Applicant's direct the Examiner's attention to reference "BT" on the Form PTO-1449 which was previously submitted in the April 1, 2005 Information Disclosure Statement. Applicants note that reference "BT" was previously submitted under seal in the

parent application, U.S. Application Serial No. 09/705,630, filed November 3, 2000, now U.S. Patent No. 6,866,866. As discussed in the February 28, 2003 Information Disclosure Statement which was submitted during the prosecution of the '866 patent, a biostudy (which resulted in the data submitted as reference BT) was performed using formulations prepared in accordance with U.S. Patent No. 6,099,859. It is noted that the exemplified formulations did not provide a T_{\max} between 8-12 hours except when the formulation prepared in accordance with Example 3 was administered at dinner. As set forth in the accompanying biostudy data, the mean T_{\max} values for the Examples of the '859 were as follows: Example 1 (fasting) 4.67 hours (*See, e.g.*, pages 1 and 3 of the biostudy); Example 2 (fasting) 4.33 hours (*See, e.g.*, pages 10 and 12 of the biostudy); Example 2 (fed a.m.) 6.80 hours (*See, e.g.*, pages 13, 14 and 16 of the biostudy); Example 3 (fed a.m.) 6.67 hours (*See, e.g.*, pages 4 and 6 the biostudy); Example 3 (Fed p.m.) 9.67 hours (*See, e.g.*, pages 17 and 20 of the biostudy). Therefore, the only instance that the T_{\max} was between 8-12 hours was Example 3 fed in the P.M. (at dinner).

In addition, pages 2, 5, 11, 15, 19 of the biostudy data includes plasma concentration v. time graphs and data for formulations prepared in accordance with Examples 1(fasting), 3 (fed), 2 (fasting), 2 (fed), and 3 (fed), respectively, of U.S. Patent No. 6,099,859; pages 8 and 9 of the biostudy data include plasma concentration v. time graphs and data for formulations prepared in accordance with Example 2 (fasting and fed) and Example 3 (fed a.m. and p.m.) of U.S. Patent No. 6,099,859; and pages 7 and 18 include plasma concentration v. time graphs and data for formulations prepared in accordance with Example 3 (fed a.m. and p.m.) of U.S. Patent No. 6,099,859.

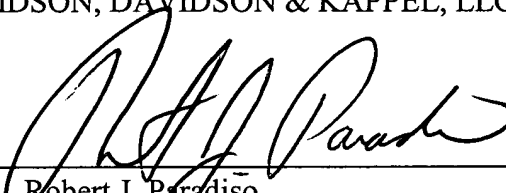
Applicants also note that a second opposition was filed in the corresponding Colombian Patent Application No. 03-036463 (a copy of the opposition is enclosed herewith). The references cited in the enclosed opposition are listed on the April 1, 2005 Form PTO-1449 as references "BS", "AM" and "AH".

Pursuant to 37 C.F.R. § 1.98 (a), the reference on the attached Form PTO-1449 has been submitted herewith. If it is determined that reference has not been submitted, the Examiner is requested to contact the undersigned so that a copy can be forwarded.

It is respectfully requested that the reference cited in the accompanying Form PTO-1449 (1 sheet) be considered and made of record.

This Information Disclosure Statement is being filed after a First Office Action but before a Final Office Action or Notice of Allowance. Pursuant to 37 C.F.R. § 1.98(c), a check for \$180.00 is enclosed to cover the required fee. However, if it is determined that any fee is due, the Examiner is authorized to charge said fee to Attorney Deposit Account No. 50-0552.

Respectfully submitted,
DAVIDSON, DAVIDSON & KAPPEL, LLC

By 
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FORM PTO-1449
(REV. 7-80)

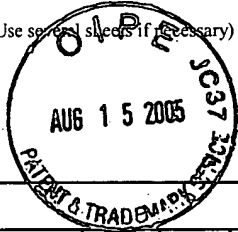
U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
300.1005CON

SERIAL NO.
10/796,411

LIST OF REFERENCES CITED BY APPLICANT

(Use separate sheets if necessary)



APPLICANTS
Chih-Ming CHEN, et al.

FILING DATE
March 9, 2004

GROUP
1615

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | | | | | | | | | | DATE | NAME | CLASS | SUB- CLASS | FILING DATE IF APPROPRIATE |
|---------------------|----|--|--|--|--|--|--|--|--|------|------|-------|---------------|-------------------------------|
| | EA | | | | | | | | | | | | | |
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FOREIGN PATENT DOCUMENTS

| | | | | | | | | | | DATE | COUNTRY | CLASS | SUB- CLASS | TRANSLATION | |
|--|----|---|---|---|---|---|---|---|--|----------|---------|-------|---------------|-------------|----|
| | | | | | | | | | | | | | | YES | NO |
| | EL | 0 | 0 | 1 | 2 | 0 | 9 | 7 | | 03/09/00 | WO(A1) | A61K | 31/64 | | |
| | EM | | | | | | | | | | | | | | |
| | EN | | | | | | | | | | | | | | |
| | EO | | | | | | | | | | | | | | |

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

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| | EP | |
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EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to applicant.